

## **REMARKS**

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and the following remarks.

### **I. Summary of Claim Amendments**

All the claims under examination have been amended to recite that the peptides and mimetics are *isolated*. This underscores the “hand of man” in the claimed invention. Claim 6 has also been amended to clarify that the recited peptide comprises H A R L and between one and 25 additional amino acids.

In addition, Applicants have corrected a typographical error in claim 23 by amending part (b) of that claim to recite a peptide having the amino acid sequence “H A R L,” just as in the original claim. Applicants thank the Examiner for bringing the error to their attention.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. None of these amendments add new matter into the application, and Applicants therefore request their entry by the Examiner.

### **II. Objection to Claims 1, 2, 23, and 25 for Allegedly Reciting Improper Markush Groups**

Claims 1, 2, 23, and 25 were objected to for allegedly reciting an improper Markush group. Office Action at page 3. Applicants respectfully traverse this ground for objection.

In making the rejection, the Examiner referenced MPEP 803.02, which states, “[b]roadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that unity.”

Unity of invention exists in claims 1, 2, 23, and 25 because the peptides recited in the Markush groups of the claims share a common utility and substantial structural feature essential to that utility. The peptides share three functional characteristics that relate to their utility: (1) an ability to bind to neural thread protein (NTP), (2) an ability to bind to immunoglobulin, and (3) an ability to bind to themselves. These three characteristics make the peptides useful in the range of diagnostic and therapeutic applications described throughout the specification. Additionally, the

peptides share a structural relation: all of them derive from the repeated “Harlil” sequences in NTP. Indeed, all but one of the peptides comprise three to seven consecutive amino acids from the Harlil repeats in NTP. For these reasons, unity of invention exists among the members of the recited Markush groups. Withdrawal of this ground for objection is respectfully requested.

### **III. Objection to Claim 23**

Claim 23 was objected to under 37 C.F.R. § 1.75 as allegedly being a substantial duplicate of claim 25. In doing so, the Examiner stated that the “claims are restricted to the extent of the elected invention and thus are deemed duplicates.” Office Action at page 4. Applicants respectfully traverse this ground for objection.

Contrary to the Examiner’s assertion, claims 23 and 25 differ in scope. Claim 23 recites 19 specific amino acid sequences, and embraces peptides having sequences that: (a) correspond exactly to the recited sequences, (b) are homologs of the recited sequences, (c) that comprise the recited sequences, and (d) that comprise homologs of the recited sequences. Claim 25, by contrast, recites only 5 specific amino acid sequences, and embraces peptides that comprise “at least one and up to 25 additional amino acids flanking” the recited sequences.

MPEP 706.03(k), which the Examiner cited, states: “court decisions have confirmed an applicant’s right to restate (i.e., by plural claiming) the invention in a reasonable number of ways,” and “a mere difference in scope between the claims has been held to be enough.”

As claim 23 is not a duplicate of claim 25, withdrawal of this ground for objection is respectfully requested.

### **IV. Rejection of Claims 1, 2, 6, 23, and 25 Under 35 U.S.C. § 101**

Claims 1, 2, 6, 23, and 25 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter because the peptides are drawn to products of nature. Office Action at page 4. Applicants respectfully traverse this ground for rejection.

Applicants have amended the claims to recite *isolated* peptides and mimetics. This amendment highlights “the hand of man” in the invention, and therefore renders the rejection moot. Thus, Applicants request withdrawal of the rejection.

**V. Rejection of Claim 6 Under 35 U.S.C. § 112, Second Paragraph**

Claim 6 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the claim “appears to recite a peptide that is at most 29 residues in length,” yet “also recites ‘having’ which is open language and would allow the peptide to be of greater than 29 residues in length.” Office Action at page 5. Applicants respectfully traverse this ground for objection.

Contrary to the Examiner’s assertion, claim 6 is definite. Claim 6 recites a peptide comprising H A R L, and between one and 25 additional amino acids. Although the transition language is open, this does not indicate that the peptide can comprise “an unlimited number of sequences on both the 3’ and 5’ ends,” as the Examiner suggested. The claim language “between one and 25 additional amino acids . . .” clearly limits the size of the functional peptide, but still permits the peptide to have additional elements, or to exist in a larger context.

For instance, the peptide may be conjugated with a label or a linker molecule element. Additionally, the peptide may be conjugated to a larger molecule such as an immunoglobulin, as in Example 1. This would be clear to one skilled in the art reading claim 6 in light of the specification. Therefore, claim 6 complies with the definite claiming requirement of 35 U.S.C. § 112, second paragraph, and Applicants respectfully request withdrawal of the rejection.

**VI. Rejection of Claims 1, 2, 6, 23, and 25 Under 35 U.S.C. § 102**

Claims 1-2, 6, 23, and 25 were rejected under 35 U.S.C. § 102 as allegedly being anticipated by U.S. Patent No. 5,716,813 (Kubota et al.) because, according to the Examiner, the patent teaches an isolated peptide of HARL in SEQ ID NO:8. Office Action at pages 5-6. Applicants respectfully traverse this ground for rejection.

Contrary to the Examiner’s assertion, SEQ ID NO:8 of the ‘813 patent does not correspond to an isolated peptide. Rather, it represents a stretch of amino acids within a larger protein, and upon which a nucleic acid probe was based. At column 15, lines 36-42, the ‘813 patent reads as follows:

. . . the recombinant DNA was hybridized with probe 2 having the base sequence as shown in SEQ ID NO:8, which had been chemically synthesized based on the amino acid sequence located at positions from 2 to 6, i.e. Asp-Trp-Ala-Glu-Ala, in

SEQ ID NO:8, followed by selecting a recombinant DNA strongly hybridized with the probe 2.

This is the only reference (outside of the sequence listing) to SEQ ID NO:8 in the entire '813 patent, and it clearly does not teach or suggest that SEQ ID NO:8 is an isolated peptide. Accordingly, the '813 patent does not anticipate the claimed invention, and withdrawal of this ground for rejection is respectfully requested.

**VII. Conclusion**

The present application is now in condition for allowance, and favorable reconsideration is respectfully requested. If the Examiner feels that a telephone interview would advance the prosecution, she is invited to contact the undersigned by telephone.

If there are any fees due in connection with the filing of this Amendment, please charge them to our Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Date

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**Marked-Up Version of the Claims**

1. (Amended) **An isolated [A]** peptide having an amino acid sequence selected from the group consisting of:

- (a) H H A R L; (portion of SEQ ID NO: 2, residues 291-295)
- (b) H A R L; (portion of SEQ ID NO: 2, residues 292-295)
- (c) H A R L I; (portion of SEQ ID NO: 2, residues 292-296)
- (d) H A R L I L; (portion of SEQ ID NO: 2, residues 46-51)
- (e) H H A R L C L; (portion of SEQ ID NO: 2, residues 90-96)
- (f) A R L I L; (portion of SEQ ID NO: 2, residues 47-51)
- (g) H H A R L I F; (portion of SEQ ID NO: 2, residues 291-297)
- (h) T H A R L I L; (portion of SEQ ID NO: 2, residues 45-51)
- (i) A R L I; (portion of SEQ ID NO: 2, residues 47-50)
- (j) A R L;
- (k) H A R L C L; (portion of SEQ ID NO: 2, residues 91-96)
- (l) A R L C L; (portion of SEQ ID NO: 2, residues 92-96)
- (m) A R C L; (SEQ ID NO: 12)
- (n) M F A R L I L; (portion of SEQ ID NO: 2, residues 263-269)
- (o) F A R L I L; (portion of SEQ ID NO: 2, residues 264-269)
- (p) F A R L I; (portion of SEQ ID NO: 2, residues 264-268)
- (q) F A R L; (portion of SEQ ID NO: 2, residues 264-267)
- (r) H A R L I F; (portion of SEQ ID NO: 2, residues 292-297)
- (s) A R L I F; (portion of SEQ ID NO: 2, residues 293-297),

and homologs thereof.

6. (Amended) **An isolated [A]** peptide **comprising [having]** the amino acid sequence H A R L (portion of SEQ ID NO: 2, residues 292-295), and **[comprising at least] between** one and **[up to]** 25 additional amino acids flanking either the 3' or 5' end of the peptide.

23. (Amended) **An isolated [A]** mimetic of a peptide having an amino acid sequence selected from the group consisting of:

- (a) H H A R L; (portion of SEQ ID NO: 2, residues 291-295)
- (b) **H A R L; (portion of SEQ ID NO: 2, residues 292-295) [H-A-R]**
- (c) H A R L I; (portion of SEQ ID NO: 2, residues 292-296)
- (d) H A R L I L; (portion of SEQ ID NO: 2, residues 46-51)
- (e) H H A R L C L; (portion of SEQ ID NO: 2, residues 90-96)
- (f) A R L I L; (portion of SEQ ID NO: 2, residues 47-51)
- (g) H H A R L I F; (portion of SEQ ID NO: 2, residues 291-297)
- (h) T H A R L I L; (portion of SEQ ID NO: 2, residues 45-51)
- (i) A R L I; (portion of SEQ ID NO: 2, residues 47-50)
- (j) A R L;
- (k) H A R L C L; (portion of SEQ ID NO: 2, residues 91-96)
- (l) A R L C L; (portion of SEQ ID NO: 2, residues 92-96)
- (m) A R C L; (SEQ ID NO: 12)
- (n) M F A R L I L; (portion of SEQ ID NO: 2, residues 263-269)
- (o) F A R L I L; (portion of SEQ ID NO: 2, residues 264-269)
- (p) F A R L I; (portion of SEQ ID NO: 2, residues 264-268)
- (q) F A R L; (portion of SEQ ID NO: 2, residues 264-267)
- (r) H A R L I F; (portion of SEQ ID NO: 2, residues 292-297)
- (s) A R L I F; (portion of SEQ ID NO: 2, residues 293-297),

and homologs of such amino acid sequences.

25. (Amended) **An isolated [A]** mimetic of a peptide having an amino acid sequence selected from the group consisting of:

- (a) A R L I; (portion of SEQ ID NO: 2, residues 47-50)
- (b) H A R L; (portion of SEQ ID NO: 2, residues 91-94)
- (c) F A R L; (portion of SEQ ID NO: 2, residues 264-267)
- (d) A R L, and
- (e) A R L C; (SEQ ID NO: 12),

wherein the [NTP] peptide comprises at least one and up to 25 additional amino acids flanking either the 3' or 5' end of the peptide.